U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 16, 2019

Via Email

John C. Bostic
Assistant United States Attorney
john.bostic@usdoj.gov

Jeffrey B. Coopersmith
Davis Wright Tremaine LLP
jeffcoopersmith@dwt.com

Kevin M. Downey
Williams & Connolly LLP
kdowney@wc.com

Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Messrs. Bostic, Coopersmith, and Downey:

I write following my July 9, 2019 letter to provide additional information regarding FDA's processing, review, and production of documents responsive to the document requests made by the Government on behalf of Defendants.

In my July 9 letter, I stated that FDA expects to complete its production within six months provided that FDA receives a waiver from the Theranos assignee to permit FDA to release Theranos trade secret and confidential commercial information to the parties in this action without redactions. This timeframe reflects FDA's best estimate given prior processing and review averages for these documents, the addition of more reviewers to the current set of approximately 3 full-time equivalent employees ("FTEs") in the next few weeks, and, of course, receipt of the waiver. This timeframe also reflects the time involved for FDA to review and redact information from the documents that is attorney work product or is privileged (attorney-client and non-Theranos deliberative process). As relayed in my June 7 and July 9 letters, FDA also must review and redact for trade secret and confidential commercial information belonging to non-Theranos third parties. 21 U.S.C. § 331(j); 21 U.S.C. § 360j(c); 18 U.S.C. § 1905; 21 C.F.R. § 20.61. For example, FDA will redact standard operating procedures ("SOPs") of Theranos's corporate partners that exist within the set of responsive documents. To be clear, with a waiver from Theranos, FDA will not redact trade secret or confidential commercial information belonging to Theranos, but it must redact such information belonging to non-Theranos entities.

FDA understands that a supplemental protective order may be requested and entered in the above-captioned action. If that supplemental protective order provides that FDA's documents will be protected from public disclosure absent agreement by FDA or a Court order, FDA will not review and redact for personal private information ("PPI") or the identities of confidential informants, if any exist. FDA expects that such a supplemental protective order will shorten the timeframe in which FDA is able to produce the

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

documents, although, as stated above, it will still need to review and redact for other privileged and protected information. The addition of a "clawback" provision in any supplemental protective order, as has been suggested to FDA, will not impact FDA's obligations to review and redact privileged and protected information, for which it is prohibited by law and professional obligation to its internal clients to protect.[1]

As I previously conveyed in my July 9 letter, FDA is, and has been, working diligently to collect, process, review, and ultimately produce all documents responsive to all six categories requested by the parties. It is not withholding responsive documents based on a determination of relevance, and it is not withholding documents that relate specifically to Theranos on the basis of the deliberative process privilege. FDA has also been investigating, and will continue to investigate, avenues to expedite processing and review of the documents it has collected, including the use of automated software to facilitate review.

FDA will continue to work as expeditiously as possible to provide the parties with the requested material, as set forth above.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel

[1] Counsel to Defendant Balwani has posed additional questions to FDA regarding specific custodians and a privilege log. FDA will respond to Defendant Balwani's counsel by separate letter.